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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/480,544	01/10/2000	JOHN H. KENTEN	0039096-0030	4434

35745 7590 07/17/2003

KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
919 THIRD AVENUE
NEW YORK, NY 10022

EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/480,544

Applicant(s)

Kenten et al.

Examiner

Arun Chakrabarti

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 23, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Jun 23, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

The request for reconsideration filed on June 23, 2003, has been considered but does not place the application in condition for allowance because of the following reasons:

In response to applicant's arguments (page 2, third paragraph) against the references (especially Malek et al. (U.S. Patent 5,130,238)) individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It has been stated clearly in the last office action what Malek teaches and what other secondary reference teaches with special reference to column and line numbers.

Applicant argues (Page 2, fourth paragraph) that Kenten et al reference does not teach the use of two probes, one having an ECL label and the other having a capture moiety.

Kenten et al clearly teaches the addition of;

(I) at least one probe sequence complementary to the RNA first template labeled with an electrochemiluminescent species comprising ruthenium-tris-bipyridine (Example I),

(ii) at least one second capture probe sequence complementary to the RNA first template labeled with a binding species selected from biotin (Examples IV-V)

Applicant then argues (Page 3, third paragraph to page 4, line 4) that the 103 rejection is improper because it is obvious to try and lacks a reasonable expectation of success. There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Kenten reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different ECL labels were actually experimentally studied and found to be functional to monitor the amplification activity (Examples 1-7). This evidence of functionality trumps the attorney arguments, which argues that

Kenten reference is an invitation to research, since Kenten steps beyond research and shows the functional product.

Applicant also argues (Page 4, lines 2-4) that PCR and NASBA are two different methods because PCR results in DNA, whereas NASBA results in RNA. This argument is not persuasive in view of the fact that RNA polymerase can also produce RNA via PCR reaction.

Applicant also argues (Page 4, second and third paragraph and page 5, second and third paragraph) that there is no motivation to combine the references and the motivation of Kenten is different from the applicant's claimed invention. This argument is not persuasive, especially in the presence of strong motivation provided by Kenten et al since Kenten et al. states , "The unexpected exponential amplification of the invention greatly simplifies the process of amplifying multiple nucleic acid sequences of interest present in a sample (Column 5, lines 1-4)". In response to applicant's argument that Kenten has motivation to use his invention which is different from the claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In view of the response to request for reconsideration, applicant's remarks has not been found persuasive and therefore has not been entered.

Never
Say this


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S CASE ACTION WORKSHEET

Application No. <div style="text-align: center;">09/480,544</div>		Legal Instrument Examiner
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CHECK TYPE OF ACTION

DATE OF COUNT _____

<input type="checkbox"/> Non-Final Rejection	<input type="checkbox"/> Restriction/ Election Only	<input type="checkbox"/> Final Rejection
<input type="checkbox"/> Ex Parte Quayle	<input type="checkbox"/> Allowance	<input checked="" type="checkbox"/> Advisory Action
<input type="checkbox"/> Examiner's Answer	<input type="checkbox"/> Reply Brief Noted	<input type="checkbox"/> Non-Entry of Late Paper
<input type="checkbox"/> Defective Notice of Appeal or Defective Appeal Brief	<input type="checkbox"/> Interference SPE <small>(Approval for Disposal)</small>	<input type="checkbox"/> Suspension SPE <small>(Initial)</small>
<input type="checkbox"/> Allowance After Examiner's Answer	<input type="checkbox"/> SIR Disposal <small>(use only after FAOM)</small>	<input type="checkbox"/> Post-Allowance Communication
<input type="checkbox"/> Miscellaneous Office Letter <small>(With Shortened Statutory Period Set)</small>	<input type="checkbox"/> Notice of Non-Responsive Amendment <small>(With One Month Time Period Set)</small>	<input type="checkbox"/> Miscellaneous Office Letter <small>(No Response Period Set)</small>
<input type="checkbox"/> Letter Requiring Formal Drawings	<input type="checkbox"/> Supplemental Action <small>(Excluding Examiner's Answer)</small>	<input type="checkbox"/> Response to a Rule 312 Amendment
<input type="checkbox"/> Restart Time Period <small>(e.g., Missing References)</small>	<input type="checkbox"/> Interview Summary	<input type="checkbox"/> Authorization to Change Previous Office Action SPE: <small>(Initial)</small>
<input type="checkbox"/> Abandonment	<input type="checkbox"/> Express Abandonment <small>Date: _____</small>	<input type="checkbox"/> Abandonment After Examiner's Answer

Examiner's Name: Arun Chakrabarti

AU: 1634